SIEMENS

Section 006: 510(k) Summary

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: k133128

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Asha Gartland Technical Regulatory Affairs Specialist
Phone Number:	(914)-524-3257
Fax Number:	(914)-524-2101
E-mail Address:	asha.gartland@siemens.com
Date Prepared:	October 16, 2013

OCT 22 2013

2. **Device Name**

Proprietary Name:	**IMMULITE® 2000 HCG Calibration Verification Material**
Measurand:	Quality Control materials for IMMULITE® 2000 HCG assay
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 HCG assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name** — Elecsys HCG CalCheck 5
   Predicate 510(k) No: K092168

4. **Device Description:** The Calibration Verification Material (CVM) contains One set of four vials each 3mL. CVM1 contains HCG-free human serum with preservatives. CVM2, CVM3 and CVM4 contain HCG added to HCG-free human serum respectively, with preservatives.

5. **Intended Use:** See Indications for Use Statement below:
   Indication for Use: The IMMULITE® HCG Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE HCG assay on the IMMULITE 2000 systems.

Special Conditions for Use Statement(s):	For prescription use only
Special Instrument Requirements:	IMMULITE® 2000 Systems
6. Technological Characteristics and Substantial Equivalence Comparison with Predicate:	A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 HCG Calibration Verification Material (CVM) is substantially equivalent to the predicate device as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device IMMULITE 2000 HCG CVM	**Predicate Device** Elecsys HCG CalCheck 5
Intended Use	The IMMULITE® HCG Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE HCG assay on the IMMULITE 2000 systems.	The Elecsys HCG CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys HCG+β reagent and Elecsys HCG STAT reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.
Analyte	HCG	Same
Matrix	Human Serum with preservatives	Same
Stability	Stable unopened until the expiration date	Same

	DIFFERENCES	
	Candidate Device IMMULITE 2000 HCG CVM	**Predicate Device** Elecsys HCG CalCheck 5
Form	Liquid	Lyophilized
Levels	4	5
Storage	≤20°C	2-8 °C
Use	Single Use Only	Not For Single Use

7. Non-Clinical Performance Testing

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the candidate device.

7.1 Stability Summary:

The stability study was conducted to validate shelf life claim for the IMMULITE 2000 HCG Calibration Verification Material (CVM) to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the CVM. The IMMULITE® 2000 HCG Calibration Verification Materials are stable up to 2.5 years when stored frozen at -20°C prior to opening.

7.1.1 Stability Protocol Summary:

The CVM study protocols are run as part of the calibrator stability testing. The stability CVMs and reference CVMs are run in duplicate (as a minimum) at the time points shown in Table 2 and the dose value determined from the reference calibrator curve.

Table 2: Stability Time Points

CVM Level	Time-Points (Days)			
LCGCVM1	1	548	730	912
LCGCVM2	1	548	730	912
LCGCVM3	1	548	730	912
LCGCVM4	1	548	730	912

7.1.2 Stability Acceptance Criteria Summary:

The Acceptance Criteria for the IMMULITE HCG Calibration Verification Material (CVM) consists of 2 parts. Part 1 consists of the Guideline acceptance criteria which require dose value of stability calibrator/CVM to fall between ±12% of assigned dose for CVM level 2 and ±8% of assigned dose for CVM levels 3 and 4. Part 2 review limits criteria which require dose value of the controls to be within 2SD of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose range of ±12% for level 2 and ±8% for levels 3 and 4 then additional data review is conducted using part 2 criteria. The acceptance criterion is summarized in Table 3.

Table 3 Acceptance criteria for stability of IMMULITE 2000 HCG CVM

CVM Level	Assigned Dose (mIU/mL)	Guideline Criteria % difference to assigned dose	Acceptable dose range (mIU/mL)	Review Limits
LCGCVM1	0.00	N/A	<0.40	Controls are within 2SD of target on each curve
LCGCVM2	9.35	±12	8.23 – 10.47	
LCGCVM3	654	±8	601.68 – 706.32	
LCGCVM4	5327	±23	4101.79 – 6552.21	

7.2 Traceability:

The IMMULITE HCG CVMs are traceable to WHO 3rd IS (75/537) and are manufactured using qualified materials and measurement procedures.

7.3 Value Assignment:

HCG CVMs are 4 level materials which are a subset of 12 level HCG calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of HCG reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. The assigned reference calibrators are prepared using HCG antigen spiked in a human serum matrix with preservatives and are traceable to WHO 3rd IS (75/537). Six levels of commercially available controls, and 30 pregnancy samples were used to validate calibrator/CVM value assignments.

The CVMs are manufactured using qualified materials and measurement procedures. The CVMs were tested on 15 replicates in total comprised of 5 runs and 3 replicates per run on 5 systems and 3 different reagent kit lots. The CVMs' dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples, spiked patient samples and controls using the assigned CVM values. The controls must fall within their target ranges.

7.4 Expected Values/Reference Range:

Each CVM level was tested for a total of 15 replicates; 5 runs and 3 replicates per run. 3 different reagent kit lots and 5 different instruments were used to gain 15 replicates. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected values are provided in the IMMULITE® 2000 CVM Calibration verification Material lot-specific package insert. The expected assay range is 1 - 5000 mIU/mL. The target values in Table 4 can be considered as guidelines.

Table 4: Target Values

Analyte target levels	**CVM Level**	**Target Mean (mIU/mL)**	**Standard Deviation (SD)**	**Guideline ±2SD Range (mIU/mL)**	
	CVM1	0.00	-	0.00	≤0.40
	CVM2	5.4	0.405	4.59	6.21
	CVM3	661	36.5	588	734
	CVM4	4965	571	3823	6107
Assay Range	1 – 5000 mIU/mL				

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

8. Conclusion:

The IMMULITE® 2000 HCG Calibration Verification Material is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys HCG CalCheck 5. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, the IMMULITE® 2000 HCG Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.
The assigned 510(k) Number: k133128

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Asha Gartland Technical Regulatory Affairs Specialist
Phone Number:	(914)-524-3257
Fax Number:	(914)-524-2101
E-mail Address:	asha.gartland@siemens.com
Date Prepared:	October 16, 2013

2. **Device Name** — **IMMULITE® 2000 Insulin Calibration Verification Material**

Proprietary Name:	Quality Control materials for IMMULITE® 2000 Insulin assay
Measurand:	Calibration Verification Material (CVM) for IMMULITE® 2000
Type of Test:	Insulin assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name** — Elecsys Insulin CalCheck 5
Predicate 510(k) No: K101075

4. **Device Description:** The Calibration Verification Material (CVM) contains one set of four vials, 2 mL each. CVM1 contains an equine serum matrix with preservatives. CVM2, CVM3 and CVM4 contain various levels of insulin in an equine serum matrix with preservatives.

5. **Intended Use:** See Indications for Use Statement below
Indication for Use: The IMMULITE® Insulin Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Insulin assay on the IMMULITE 2000 systems

Special Conditions for Use Statement(s):	For prescription use only
Special Instrument Requirements:	IMMULITE® 2000 Systems

6. Technological Characteristics and Substantial Equivalence Comparison with Predicate:	A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 Insulin Calibration Verification Material (CVM) is substantially equivalent to the predicate device as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device IMMULITE 2000 Insulin CVM	**Predicate Device** Elecsys Insulin CalCheck 5
Intended Use	The IMMULITE® Insulin Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Insulin assay on the IMMULITE 2000 systems	The Elecsys Insulin CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Insulin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.
Analyte	Insulin	Same
Form	Lyophilized	Same
Stability	Stable unopened until the expiration date	Same

DIFFERENCES		
	Candidate Device IMMULITE 2000 Insulin CVM	**Predicate Device** Elecsys Insulin CalCheck 5
Matrix	Equine serum with preservatives	Bovine serum with preservatives
Storage	≤20°C	2-8 °C
Levels	4	5
Use	Single Use Only	Not For Single Use

7. Non-Clinical Performance Testing

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use. The following tests were performed on the candidate device.

7.1 Stability Summary:

The stability study was conducted to validate shelf life claim for the IMMULITE 2000 Insulin Calibration Verification Material (CVM) to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the CVM. The IMMULITE® 2000 Calibration Verification Materials are stable up to 5 years when stored at -20°C prior to opening.

7.1.1 Stability Protocol Summary:

The CVM study protocols are run as part of the calibrator stability testing. The stability CVMs and reference CVMs are run in duplicate (as a minimum) at the time points shown in Table 2 and the dose value determined from the reference calibrator curve.

Table 2: Stability Time Points

CVM Level	Time-Points (Days)			
LINCVM1	1	1280	1460	1825
LINCVM2	1	1280	1460	1825
LINCVM3	1	1280	1460	1825
LINCVM4	1	1280	1460	1825

7.1.2 Stability Acceptance Criteria Summary:

The Acceptance Criteria for the IMMULITE Insulin Calibration Verification Material (CVM) are in 2 parts. Part 1 consists of the guideline acceptance criteria which require dose value of stability calibrator/CVM to fall between ±12% of assigned dose for CVM level 2, ±10% of assigned dose for CVM levels 3 and ±13% for CVM level 4. Part 2 review limits criteria which require dose value of the controls to be within 2SD of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose range of ±12% for level 2, ±10% for levels 3 and ±13% for CVM level 4 then additional data review is conducted using part 2 criteria. The acceptance criterion is summarized in Table 3.

Table 3: Acceptance criteria for stability of IMMULITE 2000 Insulin CVM

CVM level	Assigned Dose (µIU/mL)	Guideline Criteria % difference to assigned dose	Acceptable dose range (µIU/mL)	Review Limits
LINCVM1	0.00	N/A	<2.00	Controls are within 2SD of target on each curve
LINCVM2	7.00	±12%	6.16 – 7.84	
LINCVM3	26.1	±10%	23.49 – 28.71	
LINCVM4	418	±13%	363.66 – 472.34	

7.2 Traceability:
The IMMULITE Insulin CVMs are traceable to WHO NIBSC 1st IRP (66/304). The CVMs are manufactured using qualified materials and measurement procedures.

7.3 Value Assignment:
The Insulin CVMs are 4 level materials which are a subset of 10 level Insulin calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Insulin reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. The assigned reference calibrators are prepared using recombinant human Insulin antigen spiked into horse Serum with preservatives. Two levels of commercially available controls, and 30 patient samples (20 normal patients samples and 10 spiked samples) are used to validate calibrator/CVM value assignments.

The CVMs are manufactured using qualified materials and measurement procedures. The CVMs were tested on 26 replicates in total comprised of 9 runs and 2 or 3 replicates per run on 7 systems and 5 different reagent kit lots. The CVMs' dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples, spiked patient samples and controls using the assigned CVM values. The controls must fall within their target ranges.

7.4 Expected Values/Reference Range:
Each CVM level was tested for a total of 26 replicates; 9 runs and 2 or 3 replicates per run. 5 different reagent kit lots and 7 different instruments were used to gain 26 replicates. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected values are provided in the IMMULITE® 2000 CVM Calibration Verification Material lot-specific package insert The expected assay range is 0.2 -300 µIU/mL. The target values in Table 4 can be considered as guidelines.

Table 4: Target Values

Analyte target levels	CVM Level	Target Mean (µIU/mL)	Standard Deviation (SD)	Guideline ±2SD Range (µIU/mL)	
	CVM1	0.00	-	0.00	2.00
	CVM2	7.00	0.53	5.95	8.05
	CVM3	26.1	1.3	23.5	28.7
	CVM4	418	-	-	-
		314 * (75% CVM4+ 25% CVM1)	20.5	273	355
Assay Range	0.2 -300 µIU/mL				

*Note: CVM4 requires dilution to ensure the target value is within +10% of the top of the reportable range of the assay.

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

8. Conclusion:

The IMMULITE® 2000 Insulin Calibration Verification Material is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys Insulin CalCheck 5. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, the IMMULITE® 2000 Insulin Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.
The assigned 510(k) Number: K133128

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Asha Gartland Technical Regulatory Affairs Specialist
Phone Number:	(914)-524-3257
Fax Number:	(914)-524-2101
E-mail Address:	asha.gartland@siemens.com
Date Prepared:	October 16, 2013

2. **Device Name**

Proprietary Name:	**IMMULITE® 2000 Pyrilinks-D Calibration Verification Material**
Measurand:	Quality Control materials for IMMULITE® 2000 Pyrilinks-D assay
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 Pyrilinks-D assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name**

	IMMULITE® Unconjugated Estriol (uE3) Calibration Verification Material (CVM)
Predicate 510(k) No:	K110061

4. **Device Description:** The Calibration Verification Material (CVM) contains one set of four vials, 2 mL each. CVM1 contains a phosphoric acid and sodium chloride matrix. CVM2, CVM3 and CVM4 contain various levels of H-Deoxypyridinoline in a phosphoric acid and sodium chloride matrix.

5. **Intended Use:**
Indication for Use: See Indications for Use Statement below
The IMMULITE® Pyrilinks-D Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Pyrilinks-D assay on the IMMULITE 2000 systems

Special Conditions for Use Statement(s):	For prescription use only
Special Instrument Requirements:	IMMULITE® 2000 Systems
6. Technological Characteristics and Substantial Equivalence Comparison with Predicate:	A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 Pyrilinks-D Calibration Verification Material (CVM) is substantially equivalent to the predicate device, as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device IMMULITE 2000 Pyrilinks-D CVM	**Predicate Device** IMMULITE uE3 Calibration Verification Material (CVM)
Intended Use	The IMMULITE® Pyrilinks-D Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Pyrilinks-D assay on the IMMULITE 2000 systems.	For in vitro diagnostic use as a control for the calibration verification of the IMMULITE® Unconjugated Estriol (uE3) assays on the IMMULITE/IMMULITE 1000 and 2000 systems.
Form	Liquid	Same
Levels	4	Same
Stability	Stable unopened until the expiration date	Same
Use	Single Use Only	Same

DIFFERENCES		
	Candidate Device IMMULITE 2000 Pyrilinks-D CVM	**Predicate Device** IMMULITE uE3 Calibration Verification Material (CVM)
Analyte	Pyrilinks-D	Unconjugated Estriol
Matrix	phosphoric acid and sodium chloride	Horse serum with preservatives
Storage	≤20°C	2-8°C

7. Non-Clinical Performance Testing

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use. The following tests were performed on the candidate device.

7.1 Stability Summary:

The stability study was conducted to validate shelf life claim for the IMMULITE 2000 Pyrilinks-D Calibration Verification Material (CVM) to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the CVM. The IMMULITE® 2000 Pyrilinks-D Calibration Verification Materials (CVMs) are stable up to5 years when stored at -20°C prior to opening.

7.1.1 Stability Protocol Summary:

The CVM study protocols are run as part of the calibrator stability testing. The stability CVMs and reference CVMs are run in duplicate (as a minimum) at the time points shown in Table 2 and the dose value determined from the reference calibrator curve.

Table 2: Stability Time Points

CVM Level	**Time-Points (Days)**				
LPDCVM1	1	1280	1460	1642	1825
LPDCVM2	1	1280	1460	1642	1825
LPDCVM3	1	1280	1460	1642	1825
LPDCVM4	1	1280	1460	1642	1825

7.1.2 Stability Acceptance Criteria Summary:

The Acceptance Criteria for the IMMULITE Pyrilinks-D Calibration Verification Material (CVM) are in 2 parts. Part 1 consists of the guideline acceptance criteria which require dose value of stability calibrator/CVM to fall between ±10% of assigned dose. Part 2 review limits criteria which require dose value of the controls to be within 2SD of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose range of ±10% then additional data review is conducted using part 2 criteria. The acceptance criterion is summarized in Table 3.

Table 3: Acceptance criteria for stability of IMMULITE 2000 Pyrilinks-D CVM

CVM level	**Assigned Dose (nmol/L)**	**Guideline Criteria % difference to assigned dose**	**Acceptable dose range (nmol/L)**	**Review Limits**
LPDCVM1	0.00	N/A	<7.00	Controls are within 2SD of target on each curve
LPDCVM2	18.30	±10%	16.47 – 20.13	
LPDCVM3	49.00	±10%	44.10 – 53.90	
LPDCVM4	302.00	±10%	271.80 – 332.20	

7.2 Traceability:
The IMMULITE Pyrilinks-D CVMs are traceable to internal material which has been gravimetrically prepared. The CVMs are manufactured using qualified materials and measurement procedures.

7.3 Value Assignment:
Pyrilinks-D CVMs are 4 level materials which are a subset of 8 level Pyrilinks-D calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Pyrilinks-D reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. The assigned reference calibrators are prepared using Hydrolysed Deoxypyridiniline antigen spiked in a matrix consisting of Phosphoric acid and Sodium Chloride in deionised water. Two levels of commercially available controls and 30 patient female urine samples are used to validate calibrator/CVM value assignments.

The CVMs are manufactured using qualified materials and measurement procedures. The CVMs were tested on 15 replicates in total comprised of 5 runs and 3 replicates per run on 4 systems and 3 different reagent kit lots. The CVMs' dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples, spiked patient samples and controls using the assigned CVM values. The controls must fall within their target ranges.

7.4 Expected Values/Reference Range:
Each CVM level was tested for a total of 15 replicates; 5 runs and 3 replicates per run. 3 different reagent kit lots and 4 different instruments were used to gain 15 replicates. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected values are provided in the IMMULITE® 2000 CVM Calibration Verification Material lot-specific package insert. The expected assay range is 7 -300 nmol/L. The target values in Table 4 can be considered as guidelines.

Table 4: Target Values

Analyte target levels	**CVM Level**	**Target Mean (nmol/L)**	**Standard Deviation SD**	**Guideline ±2SD Range (nmol/L)**	
	CVM1	0.00	-	0.00	≤7.00
	CVM2	16.3	3.255	9.78	22.8
	CVM3	49.2	5.4	38.4	60.0
	CVM4	301	15	271	331
Assay Range	7 -300 nmol/L				

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

8. Conclusion:

The IMMULITE® 2000 Pyrilinks-D Calibration Verification Material is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed IMMULITE Unconjugated Estriol (uE3) Calibration Verification Material (CVM). The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, the IMMULITE® 2000 Pyrilinks-D Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.
The assigned 510(k) Number: K133128

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Asha Gartland Technical Regulatory Affairs Specialist
Phone Number:	(914)-524-3257
Fax Number:	(914)-524-2101
E-mail Address:	asha.gartland@siemens.com
Date Prepared:	October 16, 2013

2. **Device Name**

Proprietary Name:	**IMMULITE® 2000 Homocysteine Calibration Verification Material**
Measurand:	Quality Control materials for IMMULITE® 2000 Homocysteine assay
Type of Test:	Calibration Verification Material (CVM) for IMMULITE® 2000 Homocysteine assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name**

Predicate 510(k) No:	Audit™ MicroCV™ Homocysteine Linearity Set K100715

4. **Device Description:** The Calibration Verification Material (CVM) contains one set of four vials, 2mL each. CVM 1 contains a bovine protein/buffer matrix with preservatives. CVM2, CVM3 and CVM4, contain various levels of s-adenosyl-L-homocysteine in a bovine protein/buffer matrix with preservatives.

5. **Intended Use:**

Indication for Use: See Indications for Use Statement below
The IMMULITE® Homocysteine Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Homocysteine assay on the IMMULITE 2000 systems

Special Conditions for Use Statement(s): For prescription use only

Special Instrument Requirements: IMMULITE® 2000 Systems

6. **Technological Characteristics and Substantial Equivalence Comparison with Predicate:** A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 Homocysteine Calibration Verification Material (CVM) is substantially equivalent to the predicate device, as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device IMMULITE 2000 Homocysteine CVM	**Predicate Device** Audit® Micro*CV*™ Homocysteine Linearity
Intended Use	The IMMULITE® Homocysteine Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Homocysteine assay on the IMMULITE 2000 systems.	The Audit® Micro*CV*™ Homocysteine Linearity for use with Siemens Centaur® Immunoassay Systems, is intended to simulate human patient serum samples for purpose of determining linearity, calibration verification and verification of reportable range for Homocysteine.
Analyte	Homocysteine	Same
Stability	Stable unopened until the expiration date	Same
Form	Liquid	Same

DIFFERENCES		
	Candidate Device IMMULITE 2000 Homocysteine CVM	**Predicate Device** Audit® Micro*CV*™ Homocysteine Linearity
Matrix	Bovine protein/buffer matrix	Human serum
levels	4	5
Storage	≤20°C	2-8°C
Use	Single Use Only	Not For Single Use

7. **Non-Clinical Performance Testing**

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the candidate device.

7.1 Stability Summary:

The stability study was conducted to validate shelf life claim for the IMMULITE 2000 Homocysteine Calibration Verification Material (CVM) to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the CVM. The IMMULITE® 2000 Homocysteine Calibration Verification Materials (CVMs) are stable up to 3.5 years when stored at -20°C prior to opening.

7.1.1 Stability Protocol Summary:

The CVM study protocols are run as part of the calibrator stability testing. The stability CVMs and reference CVMs are run in duplicate (as a minimum) at the time points shown in Table 2 and the dose value determined from the reference calibrator curve.

Table 2: Stability Protocol Summary

CVM Level	Time-Points (Days)				
LHOCVM1	1	730	912	1095	1280
LHOCVM2	1	730	912	1095	1280
LHOCVM3	1	730	912	1095	1280
LHOCVM4	1	730	912	1095	1280

Stability Acceptance Criteria Summary:

The Acceptance Criteria for the IMMULITE Homocysteine Calibration Verification Material (CVM) are in 2 parts. Part 1 consists of the guideline acceptance criteria which require dose value of stability calibrator/CVM to fall between ±15% of assigned dose for CVM level 2, ±10% of assigned dose for CVM levels 3 and 4. Part 2 review limits criteria which require dose value of the controls to be within 2SD of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose range of ±15% for level 2 and ±10% for levels 3 and 4 then additional data review is conducted using part 2 criteria. The acceptance criterion is summarized in Table 3.

Table 3 : Acceptance criteria for stability of IMMULITE 2000 Homocysteine CVM

CVM level	Assigned Dose (µmol/L)	Guideline Criteria % difference to assigned dose	Acceptable dose range (µmol/L)	Review Limits
LHOCVM1	0.00	N/A	<2.0	Controls are within 2SD of target on each curve
LHOCVM2	4.12	±15%	3.50 – 4.74	
LHOCVM3	17.60	±10%	15.84 – 19.36	
LHOCVM4	71.50	±10%	64.35 – 78.65	

7.2 Traceability:
The IMMULITE Homocysteine CVMs are traceable to internal material which has been gravimetrically prepared. The CVMs are manufactured using qualified materials and measurement procedures.

7.3 Value Assignment:
Homocysteine CVMs are 4 level materials which are a subset of 7 level Homocysteine calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Homocysteine reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. The assigned reference calibrators are prepared using s-adenosyl-L-homocysteine spiked into a Bovine protein/buffer matrix and are traceable to internal material which has been gravimetrically prepared. Two levels of commercially available controls and 40 samples (30 spiked samples, 5 normal samples and 5 patient samples) are used to validate calibrator/CVM value assignments.

The CVMs are manufactured using qualified materials and measurement procedures. The CVMs were tested on 27 replicates in total comprised of 9 runs and 3 replicates per run on 7 systems and 3 different reagent kit lots. The CVMs' dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples, spiked patient samples and controls using the assigned CVM values. The controls must fall within their target ranges.

7.4 Expected Values/Reference Range:
Each CVM level was tested for a total of 27 replicates; 9 runs and 3 replicates per run. 3 different reagent kit lots and 7 different instruments were used to gain 27 replicates. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected values are provided in the IMMULITE® 2000 CVM Calibration verification Material lot-specific package insert. The expected assay range is 2 -50 µmol/L. The target values in Table 4 can be considered as guidelines.

Table 4: Target Values

Analyte target levels	CVM Levels	Target Mean (µmol/L)	Standard Deviation (SD)	Guideline ±2SD Range (µmol/L)	
	CVM1	0.00	-	0.00	≤2.0
	CVM2	4.11	0.43	3.25	4.97
	CVM3	17.5	0.875	15.8	19.3
	CVM4	73.0	-	-	-
		51.1* (70% CVM4 + 30% CVM1)	2.55	46.0	56.2
Assay Range	2 -50 µmol/L				

*Note: CVM4 requires dilution to ensure the target value is within +10% of the top of the reportable range of the assay.

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative; total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

8. Conclusion:

The IMMULITE® 2000 Homocysteine Calibration Verification Material (CVM) is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Audit® Micro*CV*™ Homocysteine Linearity for use with Siemens Centaur® Immunoassay Systems. The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness.

Based on the testing completed and the comparisons with predicate device, the IMMULITE® 2000 Homocysteine Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

510(k) Summary

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: k133128

1. **Submitter**

Mailing Address:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591
Contact Person:	Asha Gartland Technical Regulatory Affairs Specialist
Phone Number:	(914)-524-3257
Fax Number:	(914)-524-2101
E-mail Address:	asha.gartland@siemens.com
Date Prepared:	October 16, 2013

2. **Device Name**

Proprietary Name:	**IMMULITE® 2000 Growth Hormone Calibration Verification Material**
Measurand:	Quality Control materials for IMMULITE® 2000 Growth Hormone assay Calibration Verification Material (CVM) for IMMULITE® 2000
Type of Test:	Growth Hormone assay
Regulation Section:	21 CFR 862.1660, Quality Control Material
Classification:	Class I Reserved
Products Code:	JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)
Panel:	Clinical Chemistry (75)

3. **Predicate Device Name**

	IMMULITE® Unconjugated Estriol (uE3) Calibration Verification Material (CVM)
Predicate 510(k) No:	K110061

4. **Device Description:** The Calibration Verification Material (CVM) contains one set of four vials, 2 mL each. CVM 1 contains an equine serum matrix with preservatives. CVM2, CVM3 and CVM4 contain various levels of human growth hormone in equine serum matrix with preservatives.

5. **Intended Use:**

Indication for Use: See Indications for Use Statement below
The IMMULITE® Growth Hormone Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Growth Hormone assay on the IMMULITE 2000 systems.

Special Conditions for Use Statement(s): For prescription use only

Special Instrument Requirements: IMMULITE® 2000 Systems

6. **Technological Characteristics and Substantial Equivalence Comparison with Predicate:** A comparison of the device features, intended use, and other information demonstrates that the IMMULITE® 2000 Growth Hormone Calibration Verification Material (CVM) is substantially equivalent to the predicate device, as summarized in Table 1.

Table 1: Substantial Equivalence Comparison

SIMILARITIES		
	Candidate Device IMMULITE 2000 Growth Hormone CVM	**Predicate Device** IMMULITE uE3Calibration Verification Material (CVM)
Intended Use	The IMMULITE® Growth Hormone Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Growth Hormone assay on the IMMULITE 2000 systems.	For in vitro diagnostic use as a control for the calibration verification of the IMMULITE® Unconjugated Estriol (uE3) assays on the IMMULITE/IMMULITE 1000 and 2000 systems.
Matrix	Equine serum with preservatives	Same
Levels	4	Same
Stability	Stable unopened until the expiration date on the vial	Same
Storage	2-8°C	Same
Use	Single Use Only	Same

DIFFERENCES		
	Candidate Device IMMULITE 2000 Growth Hormone CVM	**Predicate Device** IMMULITE uE3 Calibration Verification Material (CVM)
Analyte	Growth Hormone	Unconjugated Estriol
Form	Lyophilized	Liquid

7. **Non-Clinical Performance Testing**

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the candidate device.

7.1 Stability Summary:

The stability study was conducted to validate shelf life claim for the IMMULITE 2000 Growth Hormone Calibration Verification Material (CVM) to ensure that it maintains optimal product performance on IMMULITE 2000 platforms throughout the established shelf life of the CVM. The IMMULITE® 2000 Growth Hormone Calibration Verification Materials (CVMs) are stable up to 6 years when stored at 2-8°C prior to opening.

7.1.1 Stability Protocol Summary:

The CVM study protocols are run as part of the calibrator stability testing. The stability CVMs and reference CVMs are run in duplicate (as a minimum) at the time points shown in Table 2 and the dose value determined from the reference calibrator curve.

Table 2: Stability Protocol Summary

CVM Level	Time-Points (Days)			
LGRHCVM1	1	1280	1642	2190
LGRHCVM2	1	1280	1642	2190
LGRHCVM3	1	1280	1642	2190
LGRHCVM4	1	1280	1642	2190

7.1.2 Stability Acceptance Criteria Summary:

The Acceptance Criteria for the IMMULITE Growth Hormone Calibration Verification Material (CVM) are in 2 parts. Part 1 consists of the guideline acceptance criteria which require dose value of stability calibrator/CVM to fall between ±12% of assigned dose for CVM levels 2 and 4, ±10% of assigned dose for CVM level 3. Part 2 review limits criteria which require dose value of the controls to be within 2SD of the control target value when generated from the stability calibrator curve. If the result is not within acceptable dose range of ±12% for levels 2 and 4, ±10% for levels 3 then additional data review is conducted using part 2 of the criteria. The acceptance criterion is summarized in Table 3.

Table 3: Acceptance criteria for stability of IMMULITE 2000 Growth Hormone CVM

CVM level	Assigned Dose (ng/mL)	Guideline Criteria % difference to assigned dose	Acceptable dose range (ng/mL)	Review Limits
LGRHCVM1	0.00	N/A	<0.01	Controls are within 2SD of target on each curve
LGRHCVM2	0.61	±12%	0.54 – 0.68	
LGRHCVM3	9.6	±10%	8.64 – 10.56	
LGRHCVM4	40	±12%	35.20 – 44.80	

7.2 Traceability:
The IMMULITE Growth Hormone CVMs are traceable to WHO 2nd IS (98/574). The CVMs are manufactured using qualified materials and measurement procedures.

7.3 Value Assignment:
Growth Hormone CVMs are 4 level materials which are a subset of 9 level Growth Hormone calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Growth Hormone reagents and two point adjustors. The IMMULITE calibrators and therefore CVMs are value assigned using assigned reference calibrators. The assigned reference calibrators are prepared with human Growth Hormone spiked in an equine serum matrix with preservatives. Six levels of commercially available controls and 30 patient samples (10 normal patient samples and 20 spiked samples) are used to validate calibrator/CVM value assignments.
The CVMs are manufactured using qualified materials and measurement procedures. The CVMs were tested on 27 replicates in total comprised of 9 runs and 3 replicates per run on 7 systems and 4 different reagent kit lots. The CVMs' dose values are generated using curve generated by assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. Quality control is performed by calculating the recovery of patient samples, spiked patient samples and controls using the assigned CVM values. The controls must fall within their target ranges

7.4 Expected Values/Reference Range:
Each CVM level was tested for a total of 27 replicates; 9 runs and 3 replicates per run. 4 different reagent kit lots and 7 different instruments were used to gain 27 replicates. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The expected values are provided in the IMMULITE® 2000 CVM Calibration verification Material lot-specific package insert. The expected assay range is 0.05 - 40 ng/mL. The target values in Table 4 can be considered as guidelines.

Table 4: Target Values

Analyte target levels	CVM Levels	Target Mean (ng/mL)	Standard Deviation (SD)	Guideline ±2SD Range (ng/mL)	
	CVM1	0.00	-	0.00	≤0.01
	CVM2	0.525	0.034	0.457	0.593
	CVM3	8.20	0.41	7.38	9.02
	CVM4	38.4	2.5	33.4	43.4
Assay Range	0.05 - 40 ng/mL				

Each laboratory should establish their limits for acceptability based on methodology, clinical significance and medical decision levels of the test analyte. The representative, total precision tabulated in the respective assay instructions for use may be considered as one factor when establishing local, acceptable ranges. The values provided above may be considered as guidelines. Value assignment is lot specific.

Standard/Guidance Documents Referenced:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

8. Conclusion:

The IMMULITE® 2000 Growth Hormone Calibration Verification Material is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed IMMULITE Unconjugated Estriol (uE3) Calibration Verification Material (CVM). The substantial equivalence of the device is supported by the non-clinical testing and was found to be comparable and supports the claims of substantial equivalence, product safety and effectiveness. Based on the testing completed and the comparisons with predicate device, the IMMULITE® 2000 Growth Hormone Calibration Verification Material does not raise any new questions on safety and effectiveness and the results support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 22, 2013

SIEMENS HEALTHCARE DIAGNOSTICS INC.
c/o Asha Gartland
511 Benedict Ave
TARRYTOWN NY 10591

Re: K133128
Trade/Device Name: IMMULITE® 2000 HCG Calibration Verification Material
IMMULITE® 2000 Insulin Calibration Verification Material
IMMULITE® 2000 Pyrilinks-D Calibration Verification Material
IMMULITE® 2000Homocysteine Calibration Verification Material
IMMULITE® 2000 Growth Hormone Calibration Verification Material
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, reserved
Product Code: JJX
Dated: September 27, 2013
Received: September 30, 2013

Dear Asha Gartland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements

as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S and

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k133128

Device Name:
IMMULITE® 2000 HCG Calibration Verification Material
IMMULITE® 2000 Insulin Calibration Verification Material
IMMULITE® 2000 Pyrilinks-D Calibration Verification Material
IMMULITE® 2000 Homocysteine Calibration Verification Material
IMMULITE® 2000 Growth Hormone Calibration Verification Material

Indications for Use:
The IMMULITE® HCG Calibration Verification Material (CVM) is intended for in vitro diagnostic use in the verification of calibration of the IMMULITE HCG assay on the IMMULITE 2000 systems.

The IMMULITE® Insulin Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Insulin assay on the IMMULITE 2000 systems.

The IMMULITE® Pyrilinks-D Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Pyrilinks-D assay on the IMMULITE 2000 systems.

The IMMULITE® Homocysteine Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Homocysteine assay on the IMMULITE 2000 systems.

The IMMULITE® Growth Hormone Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Growth Hormone assay on the IMMULITE 2000 systems.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health
510(k) k133128